Center for Scientific Review Center for Scientific Review Advisory Council Meeting National Institutes of Health U.S. Department of Health and Human Services

May 18, 2015

The Center for Scientific Review Advisory Council (CSRAC) convened at 8:30 a.m., Monday, May 18, 2015, at the Center for Scientific Review (CSR), 6107 Rockledge Drive, Bethesda, MD. The entire meeting was held in open session. Richard Nakamura, Ph.D., presided as chair.

Members Present

Roberta Diaz Brinton, Ph.D. Susan Essock, Ph.D. Pamela Hammond, Ph.D. Paula Hammond, Ph.D. Michael Hollingsworth, Ph.D. Stephen Mayo, Ph.D. Timothy Mitchison, Ph.D., F.R.S. Richard Nakamura, Ph.D. Harry Orr, Ph.D. Mary Sano, Ph.D. Louis Weiner, M.D.

Rene Etcheberrigaray, M.D., was the executive secretary for the meeting.

I. Welcome, Meeting Overview, and Approval of Minutes

Dr. Nakamura, CSR Director, welcomed CSRAC members, CSR staff, and other attendees in person and via webcast to the ninth meeting of the CSRAC. He asked CSRAC members to introduce themselves, with a special welcome to the new members: Drs. Paula Hammond, Timothy Mitchison, and Mary Sano. He thanked all the members for their service to ensure the quality of the peer review process remains high. CSRAC then approved the minutes from its October 20, 2014, meeting.

II. Changes in Policy and Review Criteria to Increase Scientific Rigor and Experimental Replicability

Judith Hewitt, Ph.D., Chief of the Biodefense Resources Section of the National Institute of Allergy and Infectious Diseases, discussed enhancing reproducibility, rigor, and transparency in research funded by the National Institutes of Health (NIH), in which she has been involved while on detail to the NIH Office of Extramural Research (OER).

Dr. Hewitt noted three articles by NIH scientists discussed issues related to development of a new policy, including an article by NIH Director Francis Collins and NIH Deputy Director Lawrence Tabak in the journal *Nature*. Members of Congress have called on NIH to address this issue. A prominent spot on the NIH homepage now links to resources on rigor and reproducibility for intramural and extramural scientists.

NIH Pilots Related to Reproducibility

NIH has undertaken pilots, also discussed in the *Nature* article, to address concerns about the reproducibility of research:

- Evaluation of the scientific premise in grant applications to ensure the foundation of research cited is solid to fund the next phase (for example, going from preclinical to clinical research);
- Development of checklist and reporting guidelines to learn if such tools would assist reviewers:
- Changes to the biosketch to focus on accomplishments and not publications;
- Approaches to reduce "perverse incentives" to seek to publish in high-profile journals by awarding options with a longer period of support;
- Support for replication studies, possibly at the Institute level;
- Training in all aspects of rigor and reproducibility, particularly for younger investigators;
- Other efforts, such as prize challenges and use of the PubMed Commons to engage in postpublication peer review.

Journal Initiative

In a related effort, editors of major journals have agreed on guidelines to enhance reproducibility and publicized the guidelines in their publications. Although preclinical research has driven a lot of this effort, Dr. Hewitt stressed the issues relate to all research and are based on good science. They include rigorous statistical analysis; transparency in reporting; data and material sharing; consideration of refutations; and best practice guidelines for antibodies, cell lines, and animals. The journals acknowledged many important details have been lost but are needed so other researchers can replicate or reproduce the findings.

New Policy

NIH will roll out guiding principles for Rigor & Transparency and for Sex as a Biological Variable at the same time because they are closely related. Their intent is to clarify NIH's long-standing expectations. They will raise awareness and begin culture shifts in the scientific community; prompt applicants to consider issues they may have previously downplayed or ignored; improve the way applicants describe the rigor of their research so reviewers have sufficient information; and demonstrate to stakeholders NIH's commitment to these concerns. They will capture what NIH has already put forth in the public domain and ensure NIH is investing in the best science while minimizing unnecessary burden for applicants. New instructions will help applicants provide clarity, and additional review questions will be added to the existing review criteria.

NIH will issue instructions related to the new guidelines in Fall 2015 for applications due in January 2016. Staff training will occur in Summer 2015, with reviewer training in Spring 2016.

Discussion Highlights

• *Changes to the application:* In answer to a question from Paula Hammond, Ph.D., Dr. Hewitt said the 12-page application limit will remain, but applicants will add an attachment

to explain their plans for authentication of cell lines and other key resources. The pilots worked within existing page limits.

- *Animals and antibodies:* Roberta Diaz Brinton, Ph.D., asked where in an application description of the sex of research animals will fit. Dr. Hewitt said the main proposal should contain the information. Dr. Brinton also praised the effort to pay attention to antibodies, as making the need for reproducibility of antibodies more public will improve the product.
- *Timeline:* Pamela Hammond, Ph.D., stressed the need for other organizations to become involved and asked about the timeline. Dr. Hewitt said journal editors and most scientific societies are on board though some have expressed concerns about implementation. She said NIH would encourage societies to help develop the guidelines specific to their areas of science.
- Assessment: Louis Weiner, M.D., asked how NIH will assess the new policy. Dr. Hewitt said NIH and the journals are planning evaluations. She agreed with Dr. Weiner's follow-on point that an evaluation of outcomes, rather than the process, could take decades.

III. Studying Both Sexes in NIH-Funded Preclincial Research

Janine Clayton, M.D., Director of the NIH Office of Research on Women's Health (ORWH), said ORWH began 25 years ago with a focus on ensuring that women were included in clinical research so that sex-specific research findings could be applied appropriately. The landmark Women's Health Initiative was launched around the same time and has demonstrated that studies specifically designed to answer women's health research questions can indeed change clinical practice. ORWH is now the NIH focal point for research on sex and gender influences on health and disease along the research continuum.

Dr. Clayton termed study of male cells and animals the "default," even when investigating conditions such as depression that affect more women than men. Although sex is one of many biological variables, combining male and female data can mask important male-female differences, for example related to stroke. The *Nature* article by Dr. Collins and Dr. Tabak, referred to by Dr. Hewitt, noted consideration of sex differences as one of the design elements ignored in some studies that may contribute to it problems with reproducibility in science.

She and Dr. Collins authored another *Nature* commentary to explain NIH aims to balance sex in preclinical studies. ORWH is awarding money for supplements of existing studies to add sex influences considerations, with a special interest in ensuring study of the influence of sex on studies involving cells. She gave several examples of research benefiting from the supplements.

As an indication of Congressional interest, the Consolidated and Further Continuing Appropriation Act (H.R. 83, or "Cromnibus") directs NIH to report on a biannual basis the proportion of all studies it funds that include sex as a biological variable. She noted the journals' new reproducibility guidelines also call for authors to report the sex of organisms under study. In September 2014, NIH issued a Request for Information (RFI) about considering sex as a biological variable. The vast majority of respondents agreed this consideration affects rigor, transparency, and generalization. As noted by Dr. Hewitt, NIH will release a new policy shortly,

and applicants and reviewers will have guidance about the placement, criteria, and language about sex as a biological variable in applications. Other efforts include developing resources for the scientific community; plans to evaluate the new policy; and training for applicants, staff, and reviewers.

As shown in the Knockout Mouse Project and other research, considering sex as a biological variable is part of good science. After pointing to other online resources, Dr. Clayton closed with "4 Cs" for studying sex to strengthen science: consider sex in developing the research question, collect sex-based data, characterize data by sex, and communicate the results by sex.

Discussion Highlights

Backlash: Dr. Brinton noted backlash related to whether females' estrous cycle may complicate research and claims that studying females means ignoring males. Dr. Clayton acknowledged these arguments have been made. She said many tools can account for the estrous cycle and stressed the need to study males and females to understand biology as much as possible. Further the estrous cycle in fact does not result in greater variability in females than males for a wide variety of parameters.

IV. Capacity in NIH Peer Review

Sally Amero, Ph.D., NIH Policy Review Officer, said the Office of Extramural Review (OER) tries to harmonize peer review across Institutes and Centers (ICs) while still allowing for flexibility. It also monitors the implementation of policies.

The added workload and changes related to the stimulus and Enhancing Peer Review, outcry in some quarters about reviewer expertise, and the changing nature of science led her to question the capacity of the peer review system. She wanted to find out how many reviewers NIH needs, how many it uses, and how many are available. About four years ago, OER started to collect aggregate data across the ICs. It turned out no data existed on the scope of the entire NIH peer review system. The data collected are a low estimate because a few programs are not included; they are posted in the NIH Data Book online.

She calculated what she called flow-through. Using an average of 74,000 applications received each year, the assignments that need to be made for each application (three per application), and the service of each reviewer (five applications each meeting), she calculated NIH needs 22,000 reviewers per year. NIH uses an average of 24,500 reviewers per year, with fluctuations caused by the number of mail-in reviewers. If every investigator funded with a Research Program Grant (RPG) in a given year served as a reviewer, about 28,000 reviewers would be available, more than needed.

V. Results of the Peer Review Capacity Evaluation

Luci Roberts, Ph.D., Director of the OER Division of Planning and Evaluation, followed Dr. Amero's presentation with results of a peer review capacity evaluation conducted by OER. Given that the number of applications continues to increase while the number of grantees who

could serve as reviewers remains constant, the study investigated how NIH can continue to uphold the excellence of peer review. Related to this, the study asked reviewers and Scientific Review Officers (SROs) two main questions:

- What is a reasonable expectation for review service from NIH-funded investigators?
- Which NIH-funded investigators serve as reviewers?

Expectations

The first question was answered through surveys sent to 4,000 applicant-reviewers (response rate 46 percent) and 423 SROs (response rate 64 percent). Most applicants were principal investigators (PIs) or program directors. In the past 12 months, 88 percent of those who had been asked did agree to review at least once, although more than half of the respondents had not been asked within the time period, suggesting that SROs are inviting the same subset of applicants. Most SROs said they initially try to recruit full and associate professors who have experience as a PI. More than half of the respondents indicated they had not been invited to review by NIH in the past year. Respondents who had not been invited to review were more often assistant professors or have limited experience with NIH grants.

Respondents who had served as NIH reviewers were asked about burden associated with review. Only 18 percent of reviewers said they thought the review process was more burdensome than it needed to be, mostly because of the number of applications assigned.

Dr. Roberts presented data to show the top reasons respondents indicated for accepting a request to participate as a NIH reviewer. The most frequently chosen reason was to gain grantsmanship experience, followed by networking with other scientists, and contributing to their scientific field. The continuous submission policy and increased opportunity for tenure were less frequent reasons. Time pressures and competing responsibilities were the most frequent reasons to decline.

One area of divergence between reviewer and SRO expectations related to workload. SROs responded that 7 to 9 applications per reviewer was an optimum workload, while reviewers said they preferred 4-6 applications per meeting.

Characteristics of Reviewers

Dr. Roberts briefly discussed the second research question, drawn from IMPAC II data that NIH collected from FY2009-2014 from people who had submitted at least one competing grant application. Over a five-year period, most investigators with R01-equivalent awards had served as reviewers. As funding increases, so does participation as a reviewer, despite anecdotal reports to the contrary. In addition, investigators age 46 and older are more likely to have served as a reviewer.

Finally, in a modeling exercise, the study sought to see if more reviewers with sufficient experience could be recruited if needed to handle a large influx of new applications. With assumptions related to experience and expectations for service, they determined that just over 3,000 new reviewers could be identified if needed.

Discussion Highlights

Survey response: In response to a question from Dr. Pamela Hammond, Dr. Roberts noted response rate was about 60 percent across both sexes and all races and ethnicities. Dr. Stephen Mayo questioned what is known about the non-respondents and attempts to proactively elicit responses from them. Dr. Roberts said they have conducted a non-response analysis to compare the characteristics of those who responded to those who were invited to take the survey but did not respond. Follow-up emails were sent to elicit responses, but OER did not want to be perceived as harassing current and potential reviewers to respond.

Applications per reviewer: Dr. Michael Hollingsworth questioned Dr. Amero's earlier calculation of five applications per reviewer and wondered about a possible decline in overall applications. Dr. Amero noted she averaged five applications per reviewer across all ICs and all types of review meetings—including situations where a reviewer might be assigned to review only one or very few applications. Dr. Roberts said submission rates have tapered off slightly, but the 10-year trend still reflects an increase in the number of applications submitted.

Review modalities: Dr. Paula Hammond asked about support for virtual meetings. Dr. Roberts said most respondents prefer in-person meetings, with virtual meetings the second choice.

VI. CSR Approaches to the Science of Peer Review

Dr. Nakamura made remarks about CSR and its goals as introduction to the next two presentations on specific CSR studies. The goals of CSR are to do the highest quality peer review while conducting peer review as efficiently as possible.

He noted CSR would like to develop quality measures but the measures to date, such as citation measures or journal impact factors, have been controversial.

Finding the Best Applications

Study sections must be able to rank applications for impact and merit, which means attracting the best reviewers, study section chairs, and SROs. Using data from Drs. Amero and Roberts, CSR is looking at the peer review system to ensure the top tier of scientists are serving as reviewers. CSR looked at scientists who had received at least \$1 million in funding in the last five years and found 45 percent had participated in the previous year. But among those who are also members of the Howard Hughes Medical Institute, Institute of Medicine, or National Academy of Sciences, the percentage of participation declines.

Another way to look at peer review outcomes is by looking at the number of citations that come from NIH-funded research. A recent analysis, published as a *Science* article, examined the success of peer review panels in predicting the future quality of proposed research. The study found a positive relationship between scores and outcomes, and the best-rated applications were the most productive.

Dr. Nakamura highlighted other work in progress. CSR hopes a concentration on scientific judgment can move away from reliance on citations. Surveys are conducted to provide insight into scientists' thinking. CSR is trying to understand the statistics of review more deeply and is

also looking at whether discussion adds value to scoring. Another challenge is to measure long-term output to determine true accomplishment in science. Finally, CSR wants to listen and encourage alternative approaches from the scientific community.

Discussion Highlights

• *Role of Council:* Dr. Pamela Hammond asked about activities CSRAC could undertake to improve quality and efficiency. Dr. Nakamura said the Scientific Management Review Board is examining ways to speed up NIH awards. While CSR is always looking for ways to speed up the process, SROs and reviewers need sufficient time to carefully examine applications.

VII. Study on Direct Ranking of Applications: Advantages and Limitations

Amy Rubenstein, Ph.D., SRO, presented results of a study by the CSR Office of Planning, Analysis and Evaluation, coordinated by her and Adrian Vances, Ph.D., Program Analyst, on direct ranking of applications. After reviewing the current scoring system, she highlighted reasons to consider direct ranking. With high rates of applications and low rates of awards, along with scoring compression in which many applications are on the same percentile, making funding decisions is difficult. Many top applications end up with tied scores. Direct ranking may help differentiate applications.

Advantages and Challenges of Direct Ranking

Potential advantages of a rank-order method, or direct ranking, include--

- Reviewers are not forced to give applications higher (worse) overall impact scores than they think an application deserves;
- Reviewers are required to separate out the very best applications from the rest;
- Reviewers have the opportunity to re-rank applications after discussion, which is less practical under the current system.

Challenges associated with direct ranking include—

- New investigators' applications will have to be integrated into the final rank order;
- Applications cannot be ranked with respect to the previous two rounds, as currently occurs;
- Reviewers in study sections that cover highly diverse areas may find direct ranking more difficult;
- Private ranking may lack the transparency of the current system.

Pilot Study

Thirty-two study sections participated in a pilot in the 2014-10 and 2015-01 Council rounds. In addition to usual scoring, reviewers privately ranked what they considered their top ten R01 applications. The rankings were not used in funding decisions during the pilot.

Data analysis measured the correlation between the percentiles/scores and the direct ranking results. They discussed a possible method to break ties, as well as a visualization of the correlation between rank and percentile. She presented the data on which they based their

analysis. Within a single scientific review group (SRG), they found good correlations between scores for the best applications and their rank order. It was more random for applications with worse scores.

The reviewers said direct ranking helped them prioritize applications and improved score spreading. Many reported more engagement in the discussion because of the need to rank, but also said it was difficult to rank applications that they had not read. The feedback suggested direct ranking could provide complementary information but not replace the current system.

Questions and Next Steps

With the data and feedback, Dr. Rubenstein said they hope to determine if ranking adds value to the peer review process and its potential use by SROs and/or Program staff.

Discussion Highlights

- *Bias:* In answer to a question from Mary Sano, Ph.D., Dr. Rubenstein said the pilot did not indicate that direct ranking created any demographic biases.
- *Ranking applications not read:* To address the difficulty in ranking unread applications, Harry Orr, Ph.D., asked whether assigned reviewers provided additional information. Dr. Rubenstein said, while an assigned reviewer may have indicated this during discussion, but it was not built into the process.
- *Review of new investigators:* Dr. Brinton asked about ranking new investigators' applications. Dr. Rubinstein said the pilot combined them because they were trying to compare direct rank to the percentile score.

VIII. Review Issues—CSR Surveys and Focus Group Plans

Mary Ann Guadagno, Ph.D., Senior SRO in the Office of the Director, reported on surveys on whether CSR's current best practices are optimal for achieving the NIH mission. Stakeholders surveyed include applicants, SROs, reviewers, and program officers. The evaluation is structured as a series of pilots. She reported a pilot that took place in September/October 2014 that provided quick feedback about the review experience.

Reviewers

In this survey, members of 167 chartered study sections received an email link to a survey with four agreement statements related to peer review and an opportunity to comment: ability of the panel to prioritize applications, appropriate expertise on the panel for the applications, assignment of applications to reviewers, and quality of discussion. Reviewers answered during the meeting, with a 64 percent response rate. She said the good news is that most reviewers felt positively about all four statements. Results were not reported out by SRG, but CSR staff did receive the results as feedback to make improvements as needed.

Program Officers

Program officers were also surveyed. If they had not attended a study section meeting, they were asked how CSR could facilitate their ability to follow the relevant SRGs. If they had, they were

asked four statements similar to those of the reviewers, but customized to program officers, as well as a few questions related to meeting formats. Most said they listen in by teleconference. They participated less frequently in the new Internet and virtual meeting formats, although those that had participated gave the formats more positive scores than those who had not. Looking across pilots, she pointed out that reviewers were more positive than program officers on the four statements related to prioritization, collective expertise, assignments, and discussion.

The survey found variation among program officers across NIH ICs in terms of survey response rates and meeting satisfaction. The ICs were de-identified in the results.

Many program officers provided comments. They were positive about the SROs, neutral about the real time meeting status (RTMS) tool and quality of peer review, but identified challenges related to microphone and telephone issues, roster quality, meeting formats, scoring, and meeting logistics. CSR will use the surveys to address actionable items and track progress over time.

Discussion Highlights

- *Program officer response*: Dr. Pamela Hammond asked about ways to increase the response rate among program officers. Dr. Nakamura said taking action on the issues they identified could help with response rates in the future.
- *Roster composition*: Dr. Paula Hammond asked about inputs that program officers can provide to study section rosters. Dr. Guadagno said some informal consultation with program officers occurs. Nakamura said program staff can make suggestions but it is the SRO's decision about whom to place on a review committee.

IX. Toward Understanding Stress in the Scientific Community

Dr. Nakamura presented a slide that illustrated that NIH grant success rates are at a historic low, which is a primary source of stress for scientists, reviewers, SROs, and others. Adjusting for inflation, NIH has had a 23 percent decrease in funding since 2003, while applications have increased. The odds of success of any given application are around 10 percent. The new A0 policy contributed to an increase of applications by about 10 percent. Fellowship trends indicate F31 (pre-doctoral student) applications now surpass F32s (post-doctoral students), possibly because pre-docs start applying earlier and continue to apply.

Another sign of stress centers on concern about the U.S. science and technology future. Eight countries now invest a higher percentage of their gross domestic product in research than does the United States. China has doubled its investment in research every five years for the past 30 years. He said he was not signaling out China as a problem; rather, their investments are a challenge to the United States. Other countries are also applying the lesson from the United States after World War II about the benefits of investing in research. Dr. Nakamura then discussed data showing the positive return on these investments.

Given the stress, CSR will do its part by doing the best possible review and spreading the message about the need to restore and continue U.S. dominance in science.

Discussion Highlights

• Return on investment: Dr. Brinton urged Dr. Nakamura to share the information about the return on investment of research, which CSRAC members could share with others. Dr. Weiner asked how to disseminate this information more broadly to the public and policymakers. Dr. Nakamura said Dr. Collins often speaks to members of Congress on the topic. CSR has provided the information to the Scientific Management Review Board and to reviewers, who can share the information with others. Dr. Sano noted the data could support discussions that she and others have with the public in their specific disease areas.

X. Plans for Review of CSR Study Sections by Areas of Science

Noni Byrnes, Ph.D., Director of the CSR Division of Basic and Integrative Biological Sciences, described a new process to evaluate study sections.

Proposed Plan

Under the proposed plan, CSR would conduct reviews by scientific, organizational clusters [Integrated Review Groups (IRG)]. Each cluster might comprise 12 to 20 study sections across IRGs. A senior-level CSR committee will form these clusters using a variety of inputs. Next, CSR will assemble a working group of scientifically broad senior scientists, preferably with interest in more than one study section within the cluster. They will receive information about the study sections within the cluster and guidelines for the review.

Proof of Concept

A cluster of bioengineering study sections that spanned eight IRGs was used to test the plan. The working group made recommendations for new or modified study sections, based on the science. CSR will develop a plan to implement the recommendations. Dr. Byrnes asked CSRAC whether evaluations should continue in this manner.

Discussion Highlights

- *Questions asked:* Dr. Sano asked about the questions given to the working group to focus on science aspects. Dr. Brinton, who represented CSRAC along with Dr. Mayo, replied the group was very science-driven and the report reflects their detailed analysis.
- *Education of applicants:* Dr. Mitchison commented that applicants do not always understand that peer review is reactive, rather than proactive. He said some applicants worry about their areas of science within a study section. Dr. Nakamura said this concern is a reason why study sections overlap, so an applicant has more than one option about which study section reviews his or her application.
- *CSRAC action:* Dr. Nakamura said he heard positive feedback from Council members during the discussion. The staff will develop an action plan and return to CSRAC for approval.

XI. Summary, Feedback, and Discussion of Issues for the Next Meeting

Dr. Nakamura summarized areas of action moving forward and invited CSRAC input.

Reproducibility and Biology of Both Sexes

Drawing on the presentations by Dr. Hewitt and Dr. Clayton, Dr. Nakamura said the emphasis on rigor and reproducibility and on inclusion of animals of both sexes will involve more focus on approach and significance in peer review, which may mean more conservative reviews at least in the short run.

He asked for ideas to encourage innovation and creativity while also ensuring the approach is sound. Dr. Paula Hammond suggested finding a way to instruct reviewers to recognize innovative ideas, then convey any concerns about approach. She urged review not to become too conservative. Dr. Weiner stress the need to use limited funds to support research that will advance the field, not just be methodologically sound. Dr. Brinton suggested analyzing non-reproducible studies for any common critical flaws to watch for. Dr. Nakamura suggested some of the pressures that create a non-reproducible study. Dr. Brinton said another idea may be to evaluate the trajectory as research moves to clinical studies to learn about any patterns.

Dr. Mitchison suggested some issues related to reproducibility could be reviewed outside of approach. Dr. Brinton said a senior investigator who moves too quickly from area to area without establishing depth in any one area could signal reproducibility concerns.

Dr. Sano suggested methods related to controls or other issues could be handled in a paragraph, as done in the social sciences. Dr. Paula Hammond said dissemination of the policy is important. CSR could provide examples of important questions to address, especially for new investigators. Dr. Brinton urged not providing too much of a script that applicants would simply plug in. Dr. Nakamura said NIH will issue a guide notice and CSR will develop an implementation plan. He welcomed CSRAC involvement.

Capacity of Peer Review

Referring to the presentations by Dr. Amero and Dr. Roberts, he said more stressed individuals are coming into the review process. He asked for suggestions to respond to the situation.

CSR Studies

Dr. Nakamura asked for CSRAC input in three areas: new approaches that might provide more information to program staff, anonymization studies in peer review, and various forms of surveys. Dr. Nakamura noted reviewers are interested in participating in surveys and many non-responses are due to technical issues that are being eliminated. CSR will share feedback learned from the surveys and actions that result with reviewers.

Dr. Brinton said an issue to address is how to select for innovation and creativity. Following on, Dr. Weiner said the prioritization (direct ranking) pilot shows some ways to reward innovation. Dr. Brinton warned innovation cannot be defined only in terms of technology, but the biology questions the technology can address. Dr. Weiner noted enabling technologies create new tools to ask questions about science. Dr. Mitchison said study section mechanics often reward continuation of the same types of research, which is a challenge in peer review and funding.

Dr. Susan Essock urged Dr. Nakamura to leave data about increasing application numbers and decreasing real dollars on the CSRAC agenda for future meetings. These data frame the discussion about peer review.

Dr. Nakamura asked CSR staff in the audience for any comments or questions. There were none. He then thanked CSRAC for their service.

We do hereby certify that, to the best of our knowledge, the foregoing minutes of the May 18, 2015, meeting of CSRAC are accurate and complete. The minutes will be considered at the next meeting of the Advisory Council, and any corrections or comments will be made at that time.

Rene Etcheberrigaray, M.D. Executive Secretary Center for Scientific Review Advisory Council

Richard Nakamura, Ph.D. Chair Center for Scientific Review Advisory Council